UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

June 15, 1994

Mr. William Rasin
Nuclear Energy Institute
1776 Eye Street, N.W.
Suite 300
Washington, D.C. 20006

Dear Mr. Rasin:

During the last meeting of the NRC and NEI Graded Quality Assurance (QA) Steering Groups on May 12, 1994, the staff committed to provide you with specific comments on your draft "Guideline for Industry Pilot Project — Implementation of Graded Performance-Based Approach to Quality." However, upon further consideration, the NRC Steering Group believes it would be more appropriate to first ensure that we are in agreement on the fundamental concept for a graded QA program. Therefore, the purpose of this letter is to provide the NRC Steering Group's views on some basic issues such that, if we are not in agreement, we can first address the conceptual differences and then move forward on this important initiative.

First, the purpose, or goal, for developing guidance for a graded QA program is to realize a savings from tailoring QA controls based on the safety significance of the structures, systems, and components (SSC) involved. Such an approach should be possible without any significant impact on plant safety, and would allow both the staff's and licensees' QA resources to be focused on the more safety-significant SSCs. We believe at this point that this fundamental goal may be accomplished by the development of guidance for the implementation of a graded Appendix B QA program. The pilot program should provide a meaningful evaluation of the guideline and allow us to determine if rulemaking may be necessary.

Secondly, the essential elements of any graded QA program should include the following: 1) a process that, with high confidence, will identify the appropriate safety significance of all SSCs in a reasonable and consistent manner, 2) an effective root-cause analysis and corrective action program for safety-significant SSCs, 3) the determination of appropriate QA controls for individual SSCs, or groups of SSCs, based upon safety function and significance, and 4) a means of reassessing SSC safety significance and QA related controls when new information becomes available. Each of these elements is discussed in further detail in the enclosure.

If there is agreement on the goal and elements of such a program, we can then proceed towards implementation of the program. We believe that the goal expressed above and the associated elements need to be specifically identified and discussed in NEI's guidance document. At that point we can provide specific comments on the guidance document.

DF03

Be assured that we continue to strongly support this effort. It is important that our regulatory requirements are effective and efficient and we are committed to working with you towards achieving that end.

The NRC Steering Group looks forward to your timely response to this letter. After receiving your response, we believe a meeting to discuss future activities, especially the upcoming pilot program, would be appropriate.

James L. Milhoan
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research

cc: Jack Skolds c/o NEI
William Bohlke c/o NEI

Enclosure:
As stated

Be assured that we continue to strongly support this effort. It is important that our regulatory requirements are effective and efficient and we are committed to working with you towards achieving that end.

The NRC Steering Group looks forward to your timely response to this letter. After receiving your response, we believe a meeting to discuss future activities, especially the upcoming pilot program, would be appropriate.

Original Signed by:
James L. Milhoan

James L. Milhoan
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research

cc: Jack Skolds c/o NEI
William Bohlke c/o NEI

Enclosure:
As stated

DISTRIBUTION:
Central Files
RPEB R.F.
SBlack

* See previous concurrence

OFC	SEND	RPEB:DRIL	SC:RPEB:DRIL	BC:RPEB:DRIL	DD:DRIL:NRR	ADT:NRR
NAME	TO	RMLatta:jp	RAGramm	GGZech	CERossi	AThadani
DATE	PDR?	6 / 10 /94*	6 / 10 /94*	6 / 10 /94*	6 / 13 /94*	6 / 13 /94*
COPY?	(Yes) No	Yes No	Yes No	Yes No	Yes No	Yes No

OFC	SEND		DEDR			
NAME	TO	CHeltemes	JMilhoan			
DATE	PDR?	6 / 13 /94*	6 / 17 /94	/ /94	/ /94	/ /94
COPY?	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

OFFICIAL RECORD COPY DOCUMENT NAME: RASIN.MEM

Enclosure

ESSENTIAL ELEMENTS OF A GRADED QUALITY ASSURANCE PROGRAM

1. Establishment of Risk Significance.

The nature and magnitude of an SSC's contribution to plant risk should determine the type and amount of QA controls and practices applied to that SSC. In our discussions, we have agreed that the process developed for implementing the maintenance rule, i.e., NUMARC 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," may offer a practical means for establishing the basis for a graded QA program. The philosophy applied in implementing the maintenance rule, i.e., the establishment of criteria or goals, performance or condition monitoring, and appropriate corrective actions when failures occur, should also be applicable to a graded QA program. For example, those SSCs that are determined to be risk significant within the scope of the maintenance rule are likely to be risk significant within the context of a graded QA program.

The expert panel described in NUMARC 93-01, and further expanded upon in NUMARC 93-02, "A Report on the Verification and Validation of NUMARC 93-01," would appear to have an extremely important role in both the maintenance rule and graded QA applications. The panel's role would be to establish the high, low and no safety-significant categories. In this regard, we understand that SSCs in the high safety-significant category would continue to reflect the Appendix B program as now constituted, and SSCs having no safety significance could be removed from the scope of Appendix B (in accordance with existing regulatory provisions). The real benefit from this activity is in tailoring the specific nature of needed QA controls for SSCs of low safety significance. The expert panel's role is critical to this determination and would be based upon:

a) The results of risk-significant determination methodologies, and

b) Deterministic factors associated with the nature and consequences of failure that could affect safety margins for SSCs such as passive pressure boundary components and standby safety systems.

The decision process needs to be described well enough such that it is likely to provide the classification results with reasonable confidence and consistency.

2. Effective Root Cause Analysis and Corrective Action Program.

NEI and the NRC have agreed that graded QA programs need to include an effective root cause analysis and corrective action program. This program would determine whether the failure of any SSC within a low-safety-significant category is acceptable in light of its specified safety significance and QA-related controls. Therefore, the NRC believes that the expert panel would need to pre-identify the necessary

procurement, design, installation, and other records necessary to be able to conduct effective root cause analyses and corrective action determinations. In addition, an adequate corrective action program would require that the locations and applications of SSCs similar to that which failed should also be retrievable.

Consistent with the approach agreed upon for the implementation of the maintenance rule, failures of low safety-significant SSCs would have to be evaluated. If a second failure subsequently occurs that is determined to be QA-preventable and/or is due to inadequate earlier corrective actions, the need for augmented QA controls should be considered until corrective actions are shown to be effective.

3. Determination of Appropriate QA Controls.

Once the expert panel has determined the safety significance of an SSC to be low, the panel would then determine the specific nature and extent of the QA controls and practices to be applied to the SSC to, among other things, support an effective root cause analysis and corrective action program as discussed in Item 2 above. This determination would include the consideration of the safety function of the SSC and non-maintenance related factors such as design, procurement, fabrication, construction, installation, testing, and human factor issues. This "grading" of QA controls is critical in order to assure that the margin of safety continues to be adequate and yet unnecessary economic burdens are minimized.

4. Incorporation of New Information and Operational Experience.

The final element would be a mechanism for the timely reevaluation of an earlier safety-significance determination and related lessening of QA controls when new information is obtained. This information could be the result of a change to the plant's IPE, an equipment or system modification, adverse performance monitoring results, or operating experience from other plants. The NRC believes that a graded QA program should be a dynamic process and that the consideration of new information needs to be an inherent part of the program.